## REMARKS

### I. Statement of Substance of Interview

Applicants would like to thank Examiner Stoica for the helpful suggestions during the telephonic interview held on June 16, 2008 with Applicants' representative, Victoria S. Molenda. During the interview, the rejections under 35 U.S.C. §112, second paragraph, were discussed. Examiner Stoica suggested that Applicants amend claims 1-7 and 39-40 to recite "**the** extracellular domain of a human or a mouse IL-21R." Examiner Stoica also suggested that Applicants specify the numerical upper limit of the conservative amino acid substitutions for claims 4 and 5. Examiner Stoica stated that because the specification has support for the sequences with at least 85% identity to the recited CDR sequences (e.g., at ¶ [0011]), the sequences that differ by a number of amino acids that constitute at most about 15% of the recited SEQ ID NOs possess adequate written description. Regarding claim 38, which is directed to a diagnostic kit, Examiner Stoica suggested that Applicants specify that the antibody and the reagent for detecting the antibody are in separate containers.

### II. Amendments to the Claims

Claims 1-6, 8-22, and 24-42 are presently pending, with claims 1-6, 14, 20, 22, and 39-42 being independent. Claims 1-6, 8-13, 25, and 38-42 are currently under examination. Claim 7 has been cancelled, and claims 1-6, 8-12, 15, and 38-40 have been amended. New claims 41 and 42 have been added. Support for these claims can be found throughout the specification and the claims as originally filed. Claims 1-3, 6-12, 15, and 38-40 have been amended for clarification and proper dependency. Support for the amendments to claims 4 and 5

can be found, *inter alia*, at pp. 6-7, ¶ [0011]. Support for new claims 41 and 42 can be found, *inter alia*, at p. 36, ¶¶ [0087]-[0088]. Therefore, no new matter has been added by way of these amendments.

Applicants make the present amendments solely to expedite prosecution. Applicants reserve the right to file applications directed to subject matter removed by way of the present amendments, as well as other matter disclosed in the specification. Entry of the amendments and consideration of the remarks presented herein is respectfully requested.

III. Rejections under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 1-13, 15, and 38-40 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Office Action, at pp. 2-3.

In order to expedite prosecution, claims 1-6 and 38-40 have been amended in accordance with the Examiner's suggestion during the telephonic interview of June 16, 2008. Claim 7 has been canceled. As claims 8-13, and 15 depend from claims 1-6, Applicants respectfully submit that these claims are also in condition for allowance. Therefore, Applicants respectfully request that this indefiniteness-based rejection be reconsidered and withdrawn.

IV. Rejection under 35 U.S.C. §112, First Paragraph – Written Description

A. Rejection of Claims 4 and 5

The Examiner rejected claims 4 and 5 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Office Action, at pp. 4-5.

The Examiner alleged that although the claims contain a functional requirement that the antibody comprising conservative amino acid substitutions must bind to the extracellular domain of a human or a mouse IL-21R and a structural requirement of the conservative amino acid substitutions made in the CDRs of the respective antibodies, the claims do not contain an upper limit to the number of substitutions that can be made. *Id.* Additionally, the Examiner alleged that there is no indication whether there are any non-substitutable residues that are necessary for binding of the receptor, or whether the binding has to be to exactly the same epitope. *Id.* Thus, the Examiner alleged that the specification does not provide adequate written description of the claimed genus. *Id.*

Applicants respectfully disagree with this rejection; however, as discussed above and solely to expedite prosecution, Applicants presently amend claims 4 and 5 as suggested by the Examiner. Therefore, Applicants respectfully submit that claims 4 and 5 satisfy the written description requirement of 35 U.S.C. §112, first paragraph, and request reconsideration and withdrawal of this written description-based rejection and allowance of the pending claims.

B. Rejection of Claim 39

The Examiner rejected claim 39 under 35 U.S.C. §112, first paragraph, as allegedly lacking adequate written description. Office Action, at pp. 5-7. The Examiner alleged that description of the antibody by less than three CDRs is inadequate, and also alleged that because claim 39 may be construed as lacking all three CDRs and combining the repertoire with a donor nucleic acid encoding an amino acid sequence of just one or two CDRs, the claim lacks adequate written description. *Id.* Applicants respectfully traverse this rejection.

Claim 39 presently recites an antibody with a $V_H$ domain that ultimately comprises SEQ ID NOs:68, 69, and 70. Similarly, new claim 41 recites an antibody with a $V_L$ domain that ultimately comprises SEQ ID NOs:71, 72, and 73. Therefore, both claims 39 and 41 recite antibodies comprising at least three CDRs.

For at least these reasons, Applicants respectfully submit that claim 39 satisfies the written description-based requirement under 35 U.S.C. §112, first paragraph, and respectfully request reconsideration and withdrawal of this written description-based rejection of the claim.

V. Rejection under 35 U.S.C. §112, First Paragraph – Enablement

The Examiner rejected claim 7 as allegedly failing to comply with the enablement requirement under 35 U.S.C. §112, first paragraph. Office Action, at pp. 7-8. The Examiner alleged that it would take undue experimentation to determine which antibody binds to exactly the same epitope with the antibody comprising an amino acid sequence selected from the group consisting of SEQ ID NOs:65, 66, and 67. *Id.*

Applicants respectfully disagree with the Examiner. However, solely to expedite prosecution, Applicants presently cancel claim 7. Therefore, Applicants respectfully submit that the Examiner's rejection is now moot.

VI. Rejection under 35 U.S.C §102

The Examiner rejected claim 39 under 35 U.S.C. §102(b) as anticipated by, or in the alternative, under 35 U.S.C. §103(a) as obvious over, Hodge (WO200069880). Office Action, at pp. 9-10. The Examiner contends that it may be construed that an antibody fragment

lacking a CDR 1, 2, or 3 encoding region might mean lacking all CDRs, and the combining of the repertoire with a donor encoding nucleic acid sequence of just one or two CDRs would lead to an antibody having less than three distinctive CDRs. *Id.* The Examiner alleges that while Hodge is silent about any particular CDRs, due to the breadth of the claim, it appears that the antibody of Hodge would have contained at least a number of the CDR regions enumerated in the instant application. *Id.* Applicants respectfully traverse the rejection.

Claim 39 presently recites an antibody comprising all three distinctive CDRs. Additionally, Applicants submit that the antibodies of Hodge were not produced by the method recited in claim 39. Antibodies of Hodge were made by injecting mice with an IL-21R-IgG fusion protein, followed by standard monoclonal antibody selection technology. *See,* Hodge, Example 4.

Moreover, as Applicants argued in their Amendment, dated October 3, 2007, in order to establish anticipation by inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. Inter. 1990) (emphasis original). Thus, the Examiner must provide a basis in fact and/or technical reasoning to demonstrate that the antibodies of Hodge necessarily comprise all three CDR sequences recited in claim 39. As the antibodies of Hodge were not produced using the methods of the instant claim and do not necessarily comprise any, much less all, CDRs recited in claim 39, Applicants respectfully submit that Hodge does not inherently anticipate the antibodies of instant claim 39.

Hodge also does not make the antibodies of claim 39 obvious. Hodge does not suggest or provide any motivation to make antibodies by the method recited in claim 39. Hodge also does not suggest or provide any motivation to make the antibodies with specific CDR sequences recited in claim 39. Therefore, Applicants respectfully submit that Hodge does not make instant claim 39 obvious.

For at least these reasons, Applicants respectfully submit that Hodge does not anticipate, or render obvious claim 39, and respectfully request reconsideration and withdrawal of the anticipation-based, or alternatively, the obviousness-based, rejection of claim 39.

## CONCLUSION

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns have been answered and overcome, that the presently claimed invention satisfies 35 U.S.C. §§112, 102, and 103, and that the instant claims are neither disclosed nor suggested by any art of record. Accordingly, reconsideration and allowance of all claims are earnestly solicited.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below-listed address.

Respectfully submitted,

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